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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/675,855 | 09/25/2003 | Edward Draper | 20030322.ORI | 3955 |
| 23595 | 7590 | 06/14/2007 | EXAMINER | |
| NIKOLAI & MERSEREAU, P.A. 900 SECOND AVENUE SOUTH SUITE 820 MINNEAPOLIS, MN 55402 | | | HOFFMAN, MARY C | |
| | | ART UNIT | | PAPER NUMBER |
| | | 3733 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|-----------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/675,855 | DRAPER, EDWARD |
| Examiner | Art Unit | |
| Mary Hoffman | 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 March 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7,9-24 and 26-34 is/are pending in the application.
 - 4a) Of the above claim(s) 10-13,17,22,23 and 26-34 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7,9,14-16,18-21 and 24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 September 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/05/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the restriction/election of species requirement in the reply filed on 03/30/2007 is acknowledged. The traversal is on the ground(s) that the apparatus cannot be used with another method, e.g. on long bones, and that the indicated species are interchangeable . This is not found persuasive because the apparatus could be used in another method, such as to heal fractures in a different location of the body. The indicated species, although interchangeable according to Applicant's invention, comprise differing structural limitations and would require different searches.

It is noted that comparison of the claims with Species 1, Figures 3E (included in the same species group as FIGS. 3A,3C), and the specification shows, however, that the species of Figures 3A,3C, 3E does not have laterally and angularly displaced link members (this feature is shown in the embodiment of FIG. 7) as required in claims 22-23.

Claims 10-13, 17, 22-23 and 26-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/30/2007.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on 3/28/2001. It is noted, however, that applicant has not filed a certified copy of the United Kingdom application as required by 35 U.S.C. 119(b).

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Ref. #'s 72 and 73 are not found in specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Facciolo et al. (U.S. Patent No. 5,662,648)

Facciolo et al. disclose an apparatus for controlling the load on articular cartilage forming part of an articular joint connecting a first bone to a second bone of a human or animal joint comprising a first fixation assembly (ref. #52) for attachment to the first bone; a second fixation assembly (ref. #52') for attachment to the second bone; a link assembly (ref. #43) coupled to the first fixation assembly by a first pivot (ref. #49) and coupled to the second fixation assembly by a second pivot (ref. #49'), the first and second fixation assembly thereby each being angularly displaceable relative to the link assembly; and wherein the apparatus as attached to the bones controls the load on articular cartilage in an articular joint formed by the bones. The first fixation assembly includes at least one pin (ref. #45) for engaging with the first bone. The first fixation assembly includes a clamp for mounting a plurality of pins each for engaging with the first bone, the plurality of pins being spaced along the length of the first fixation assembly. The link assembly includes a fixed separation member (ref. #48) for maintaining the first and second pivots at a fixed distance of separation. The apparatus further including means for limiting the angular displacement of the first fixation

assembly relative to the link assembly and/or means for limiting the angular displacement of the second fixation assembly relative to the link assembly (ref. #1). The apparatus further including means for varying separation of the first fixation assembly and the second fixation assembly as a function of the angular displacement of either fixation assembly relative to the link assembly (ref. #1). The apparatus further including a drive member coupled to the first fixation assembly and to the second fixation assembly for controllably varying the angular displacement of the first and second fixation assemblies relative to one another (ref. #1).

Claims 1-3, 7, 9 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Slocum (U.S. Patent No. 5,578,038)

Slocum discloses an apparatus for controlling the load on articular cartilage forming part of an articular joint connecting a first bone to a second bone of a human or animal joint comprising a first fixation assembly (28a) for attachment to the first bone; a second fixation assembly (28b) for attachment to the second bone; a link assembly (ref. #28c) coupled to the first fixation assembly by a first pivot (30a) and coupled to the second fixation assembly by a second pivot (30b), the first and second fixation assembly thereby each being angularly displaceable relative to the link assembly; and wherein the apparatus as attached to the bones controls the load on articular cartilage in an articular joint formed by the bones. The first fixation assembly includes at least one pin for engaging with the first bone (ref. #43a,b). The first fixation assembly includes a clamp for mounting a plurality of pins each for engaging with the first bone (ref. #44), the plurality of pins being spaced along the length of the first fixation

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assembly. The first fixation assembly is coupled to the link assembly by way of a first pivot in a manner selected from the group consisting of those having one and two degrees of rotational freedom. The link assembly includes a fixed separation member for maintaining the first and second pivots at a fixed distance of separation. The apparatus further including means for limiting the angular displacement of the first fixation assembly relative to the link assembly and/or means for limiting the angular displacement of the second fixation assembly relative to the link assembly (ref. #34). The apparatus further including means for varying separation of the first fixation assembly and the second fixation assembly as a function of the angular displacement of either fixation assembly relative to the link assembly (ref. #34).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Facciolo et al. (U.S. Patent No. 5,662,648) in view of Howard (U.S. Patent No. 6,176,860).

Facciolo et al. disclose the claimed invention except for the first fixation assembly including engagement means for engaging at least one bone pin, the engagement

means being independently rotatable about a longitudinal axis and a transverse axis of the first fixation assembly.

Howard et al disclose the first fixation assembly including engagement means for engaging at least one bone pin, the engagement means being independently rotatable about a longitudinal axis and a transverse axis of the first fixation assembly (see ref. #78) in order to provide accommodation for the bone pins (col. 5, lines 44-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Facciolo et al. with engagement means for engaging at least one bone pin, the engagement means being independently rotatable about a longitudinal axis and a transverse axis of the first fixation assembly in view of Howard in order to provide accommodation for the bone pins.

Claims 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Facciolo et al. (U.S. Patent No. 5,662,648).

Facciolo et al. disclose the claimed invention except for pair of link assemblies/a second corresponding apparatus for coupling thereto

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Facciolo et al. having pair of link assemblies/a second corresponding apparatus for coupling thereto, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. See evidentiary patents 4,696,293 to Ciullo (FIG. 10) and 5,976,125 to Graham (FIG. 3), both cited by Applicant.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Facciolo et al. (U.S. Patent No. 5,662,648) in view of Boland (U.S. Patent No. 4,576,158).

Facciolo et al. discloses the claimed invention except for a sensor, such as a strain gauge, adapted to monitor the load.

Boland discloses a sensor, a strain gauge, adapted to monitor the load in order to determine the stability of the orthopedic device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Facciolo et al. with a strain gauge in view of Boland in order to determine the stability of the orthopedic device.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slocum (U.S. Patent No. 5,578,038) in view of Howard (U.S. Patent No. 6,176,860).

Slocum disclose the claimed invention except for the first fixation assembly including engagement means for engaging at least one bone pin, the engagement means being independently rotatable about a longitudinal axis and a transverse axis of the first fixation assembly.

Howard et al disclose the first fixation assembly including engagement means for engaging at least one bone pin, the engagement means being independently rotatable about a longitudinal axis and a transverse axis of the first fixation assembly (see ref. #78) in order to provide accommodation for the bone pins (col. 5, lines 44-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Slocum with engagement means for

engaging at least one bone pin, the engagement means being independently rotatable about a longitudinal axis and a transverse axis of the first fixation assembly in view of Howard in order to provide accommodation for the bone pins.

Claims 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slocum (U.S. Patent No. 5,578,038).

Slocum disclose the claimed invention except for pair of link assemblies/a second corresponding apparatus for coupling thereto

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Slocum having pair of link assemblies/a second corresponding apparatus for coupling thereto, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. See evidentiary patents 4,696,293 to Ciullo (FIG. 10) and 5,976,125 to Graham (FIG. 3), both cited by Applicant.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slocum (U.S. Patent No. 5,578,038) in view of Boland (U.S. Patent No. 4,576,158).

Slocum discloses the claimed invention except for a sensor, such as a strain gauge, adapted to monitor the load.

Boland discloses a sensor, a strain gauge, adapted to monitor the load in order to determine the stability of the orthopedic device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Slocum with a strain gauge in view of Boland in order to determine the stability of the orthopedic device.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH 

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER